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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/071,826 | 02/08/2002 | Mitchell F. Brin | 17326CIP2 (BOT) | 2841 |
| 51957 | 7590 | 05/04/2007 | | |
| ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599 | | | EXAMINER HARRIS, ALANA M | |
| | | | ART UNIT 1643 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/071,826

Applicant(s)

BRIN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 11, 34 and 35 are pending.

Claims 1, 4, 6, 8-10, 12-15, 18-20, 32 and 33 have been cancelled.

Claims 11, 34 and 35 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

2. The rejection of claims 1, 4, 6, 8-10, 12-15, 18-20, 32 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a mammary gland disorder with *Clostridial neurotoxin botulinum* toxin A and *Clostridial difficile* toxin A, does not reasonably provide enablement for treating a mammary gland disorder with any Clostridial neurotoxin or preventing development of a mammary gland neoplasm/carcinoma is withdrawn in light of Applicants' cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas. (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964). The publication teaches the local administration of botulinum toxin type A to a patient suffering from a disease or conditions such as excessive sweating, lacrimation and mucus secretions, see abstract; page 1, section 0014; page 2, section 0017; and page 4, Example 5. The publication does not teach treating a mammary gland disorder with administration of the recited dosages in claims 11 and 34 to the mammary gland.

However, Wald and Kakulas teach apocrine gland carcinoma of the breast, which releases a substance, see page 203, column 1, last paragraph. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the two documents because the publication teaches treating various disorders with botulinum toxins and suggests modifications can be made, see page 5, section 0069. One of ordinary skill in the art would have been motivated to treat apocrine gland carcinoma of the breast with botulinum toxin A using the designated dosages with a reasonable expectation of success by teachings well known in the art, because of the successful treatment of secretions and it is art known that dosages of any composition for treatment must be adjusted and optimized, see publication, page 2, sections 0026 and 0027; and page 4, section 0061.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
Alana M. Harris, Ph.D.
17 April 2007